



Docket No. 46745 (1758)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: J. Weidanz, et al.
SERIAL NO.: 08/813,781 EXAMINER: M. Lubet
FILED: March 7, 1997 GROUP: 1644
FOR: FUSION PROTEINS COMPRISING BACTERIOPHAGE COAT
PROTEIN AND A SINGLE-CHAIN T CELL RECEPTOR

DECLARATION OF KIMBERLYN F. CARD
UNDER 37 C.F.R. §1.132

Dear Sir:

1. I, Kimberlyn F. Card declare and say that I am a resident of the United States. My residence address is 1120 SW 87th Avenue, Pembroke Pines, Florida, 33025.

2. I hold a B.A. degree from the University of Vermont. I am currently an associate scientist at Sunol Molecular Corporation 2810 North Commerce Parkway, Miramar Florida 33025. I have experience in the fields of immunology, bacteriology, protein chemistry and molecular biology. My *curriculum vitae* is attached, and illustrates my expertise and experience in these and other areas.

3. I am a co-inventor of claims 1, 2, 4, 7, 8, 14, 67, 69, 71 and 72 in the above-identified patent application (subject application). I personally performed and/or assisted in research leading to the claimed invention.

4. I have been asked to address whether a particular DNA vector called pKC44 includes sequence encoding a fragment of a T cell receptor C β sequence. It does. The pKC44 vector includes sequence that encodes the C β fragment.

5. In particular, Figure 2 of the subject application shows a "family tree" of various DNA vectors. This figure clearly shows addition of the V beta C beta region to a vector called pKC42. A resulting construct is the pKC44 vector.

6. Figure 2 from the subject application further shows that added C beta sequence was taken as V beta C beta sequence from a vector called pKC35. The pKC35 vector was made from another vector called pKC30 which vector, in turn, was made from another vector called pKC24.

7. The pKC35 vector was a source for the C beta sequence encoded by the pKC44 vector. More particularly, the C beta sequence, taken as a V beta C beta construct linked to the VIII gene from the pKC35 vector, was used to create pKC44.

8. The pKC35 V beta C beta sequence was made in a PCR amplification of another vector called pKC18. Primers KC122 and KC118 were used to accomplish the PCR reaction. Those primers are disclosed in Figure 22 of the subject application, for example. The orientation of the KC118 primer with respect to the pKC18 gene amplified a fragment of the C beta sequence. The resulting PCR reaction made a V beta C beta fragment with 5' Xho I and 3' Xma I restriction enzyme sites.

9. The V beta C beta fragment created by the PCR amplification of the pKC18 vector was subcloned into the pKC24 vector to make the pKC30 vector which was used to make the pKC35 vector. As stated, the C beta sequence from pKC35 was subcloned into the pKC42 vector to make the pKC44 vector. The pKC44 vector includes sequence encoding the C beta fragment from the pKC18 vector.

10. The manipulations referred to in paragraphs 4-9, above, are summarized in Appendix 1. The appendix shows, among other things, that the pKC44 vector includes sequence encoding the C beta fragment from the pKC18 vector.

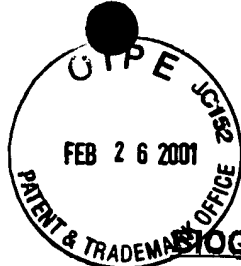
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11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that those statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

2/21/01
Date

Kimberlyn F. Card
Kimberlyn F. Card

162678



BIOGRAPHICAL SKETCH

KIMBERLYN F. CARD

EDUCATION (in reverse chronological order)

<u>Institution and Location</u>	<u>Degree</u>	<u>Years</u>	<u>Field of Study</u>
Florida International University Miami, Florida	—	1992-1993	Molecular Biology & Immunology Classes
University of Vermont Burlington, Vermont	B. A.	1985-1989	Biology

PROFESSIONAL CLASSES

22nd Annual Course in Cytometry: Research Methods and Applications
Bowdoin College Brunswick, ME (June 2000)

RESEARCH AND PROFESSIONAL EXPERIENCE (in reverse chronological order)

2000- Associate Scientist; Sunol Molecular Corporation
1996-2000 Research Associate; Sunol Molecular Corporation
1994-1996 Research Associate; Dade International/Baxter Diagnostics Inc.
1990-1994 Research Assistant; Dade International/Baxter Diagnostics Inc.
1989-1990 Research Associate I; Cambridge Biotech Corporation

AWARDS (in reverse chronological order)

Charles Irwin Travelli Scholarship; University of Vermont (1985-1989)
Valedictorian; Fair Haven Union High School Fair Haven, VT (1985)

BRIEF BIOGRAPHICAL SKETCH

At Cambridge Biotech, I was involved in the characterization of immune responses in laboratory animals using antigen specific proliferation assays as well as cytotoxic lymphocyte (CTL), tumor necrosis factor (TNF), and ELISA assays.

As a research assistant/associate at Dade, I developed and characterized monoclonal antibodies using traditional hybridoma technology. My training was later expanded to include molecular biology techniques, specifically the cloning and expression of recombinant proteins and antibodies.

At Sunol, I am responsible for cloning and characterizing single-chain T cell receptor molecules and other recombinant proteins expressed in either *E. coli* or mammalian cell expression systems. Characterization includes ELISA, flow cytometry, and cellular assays.

PUBLICATIONS

J. A. Weidanz, K. F. Card, A. Edwards, R. Perlstein, and H. C. Wong. Display of Functional $\alpha\beta$ Single-Chain T Cell Receptor Molecules on the Surface of Bacteriophage. (1998) Journal of Immunological Methods. 221:59-76.

ABSTRACTS

T Cell Receptor Based Immunotherapeutics. J. Weidanz, E. Thomson, P. Chavallaz, V. Wittman, Iling Wong, and K. Card. Sunol Molecular Corp. Immunology 2000 AAI/CIS Joint Annual Meeting, Seattle, WA. May 2000.

Generation and Characterization of a Monoclonal Antibody to Factor X Which Depletes Greater Than 99% Factor X Activity in Plasma. S. Tang, K. F. Card, L. Mooley, M. Lopez, R. Viskup, A. Edwards, K. Arbuthnott, P. Rhode, H. Pelzer, and H. C. Wong. Baxter Diagnostics, Inc. XIVth Congress of the International Society on Thrombosis and Haemostasis, New York, NY. July 1993.

Saponin Adjuvant Induced Enhancement of Cellular Immune Response to an Experimental Recombinant HIV-1 env Vaccine. K. F. Card, M. Newman, C. Kensil, and J.-Y. Wu. Cambridge Bioscience Corp. XVth New England Immunology Conference, Woods Hole, MA. October 1990.

Saponin Adjuvant Induced Enhancement of Cell-Mediated Immune Responses to an Experimental HIV-1 Vaccine. J.-Y. Wu, C. Kensil, K. L. Frazier, and M. Newman. Cambridge Bioscience Corp. ASBMB/AAI Joint Meeting, New Orleans, LA. June 1990.

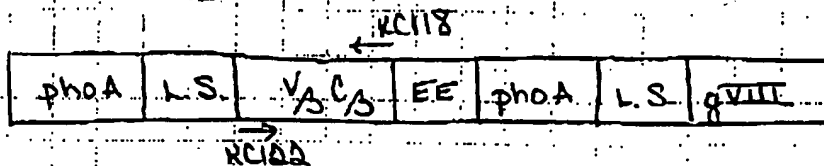
ACKNOWLEDGMENTS

Mark J. Newman, Jia-Yan Wu, Richard T. Coughlin, Cheryl I. Murphy, Jonathan R. Seals, Michael S. Wyand, and Charlotte R. Kensil. Immunogenicity and Toxicity Testing of an Experimental HIV-1 Vaccine in Nonhuman Primates. (1992) Aids Research and Human Retroviruses. 8:1413-1418.

J.-Y. Wu, C.H. Riggin, J.R. Seals, C.I. Murphy, and M.J. Newman. In Vitro Measurement of Antigen-Specific Cell-Mediated Immune Responses Using Recombinant HIV-1 Proteins Adsorbed to Latex Microspheres. (1991) Journal of Immunological Methods. 143:1-9.

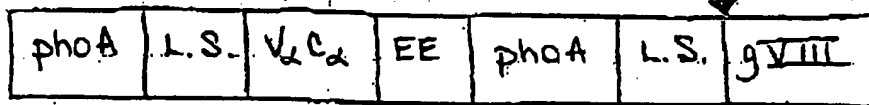


pkc18



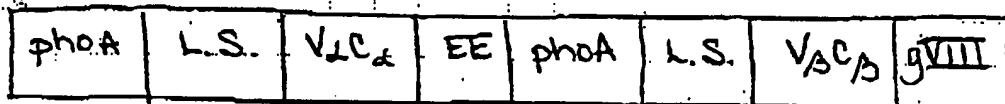
PCR fragment = 5'-xhoI/3'xmaI $V_{\Delta}C_{\Delta}$
cloned into pkc24

pkc24



resulting vector = pkc30

pkc30



added PCR-generated g^{VIII} fragment
to create pkc35

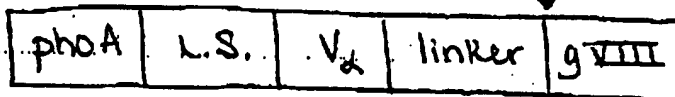
pkc35

looks like pkc30 above

cut out $V_{\Delta}C_{\Delta}$ fragment (plus g^{VIII})
with 5'-xhoI - 3'-EcoRI

Cloned into pkc42

pkc42



resulting vector = pkc44

pkc44

